Jim Doyle
Governor

Helene Nelson
Secretary

State of Wisconsin

Department of Health and Family Services

DIVISION OF HEALTH CARE FINANCING

1 WEST WILSON STREET
P O BOX 309
MADISON WI 53701-0309

Telephone: 608-266-8922
FAX: 608-266-1096
TTY: 608-261-7798
www.dhfs.state.wi.us

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Dear Prescriber:

You are being contacted because you prescribe brand name clozapine (Clozaril®). Attached to this letter are the names of your patients who are on Medicaid, BadgerCare or SeniorCare and have filled a prescription for brand name Clozaril® in the past two months.

Effective September 1, 2004, Wisconsin Medicaid, BadgerCare and SeniorCare will require prior authorization (PA) for brand medically necessary drugs, including Clozaril®. This letter describes the new policy and what you need to do to ensure the safe transition for your Medicaid patients currently taking brand name Clozaril®. It also describes the process for seeking PA under the new policy.

Prescriber Steps for Medicaid Patients on Clozaril®

- **Counsel your patients taking brand name Clozaril®**. Help your patient understand what the change is and that most patients can be switched without adverse effects.
- **Authorize the change to generic clozapine.** Medicaid patients taking brand name Clozaril® will need a new prescription for generic clozapine. You or a nurse working with you should contact the pharmacy prior to September 1, 2004, with a new prescription order.
- **Complete the PA for brand name Clozaril®.** If your patient should remain on brand name Clozaril®, contact the pharmacy to begin the PA process
- **Start new patients on a generic formulation.** Any new patient will be expected to start on generic clozapine rather than brand Clozaril®. Any patient who is admitted to the hospital where generic clozapine is used will be expected to remain on generic clozapine after discharge, unless it is clinically demonstrated that the person had a therapeutic failure, or an adverse or allergic reaction to generic clozapine.

Process to Switch to Generic

1. Authorize the Change. To switch your patients from brand to generic clozapine:

    - You or a nurse working with you should contact the patient's pharmacy, prior to September 1, 2004, with a new prescription that does **NOT** include "brand medically necessary."

    - When a patient arrives at the pharmacy prior to September 1, 2004, and has an existing prescription order for brand name Clozaril®, your office will be contacted for authorization to dispense generic clozapine. If you cannot be reached, the pharmacy may request a PA for up to a 30-day supply of brand name Clozaril® through an electronic PA process to allow you time to respond. This is a one-time exemption that will expire on September 30, 2004.

2. Counsel Patients

    - It is important that you, the patient's case manager, or a nurse from your office counsel patients about the upcoming change in their medication. Misunderstandings can be avoided and acceptance improved if patients are given factual information and have an opportunity to have their questions answered. A copy of a brochure that can be used with patients to help explain the change is enclosed. Additional copies of the brochure are available on the Medicaid web site at: dhfs.wisconsin.gov/medicaid

    - Some patients may react to the pill being "different." This is not a pharmacological response, but can still be a stress that can cause clinical problems, including a change in the patient's comfort to take the "new medication," even though it is really the same medication he or she has been on. Almost always, reassurance that this is the same medication and comfort on the part of the clinical staff can help the patient get through this period of potential difficulty. At times, a dose adjustment or additional monitoring may be needed. In rare cases, this may cause such problems that the patient needs to return to brand name Clozaril®. If the patient needs to return to brand name Clozaril®, follow the instructions in the attached Wisconsin Medicaid and BadgerCare update to obtain PA.

3. Monitoring

    - Clozaril® and generic clozapine are different from most other medications due to the requirement for a lab monitoring system. Each pharmaceutical company manufacturing clozapine has a monitoring system in place. If the prescriber makes arrangements with the pharmacy in advance to switch the patient's prescription order to generic clozapine, the pharmacy can arrange the switch seamlessly to the new monitoring system. This will reduce the need for patients to wait for their prescription while the pharmacist makes the necessary calls to switch to the new monitoring system.

    - Since the brand and generic medications are chemically identical, there is generally no need to titrate, adjust dose, or to obtain serum levels. There are potential differences in

dissolution rate from the use of different binders, and in some rare cases there have been reports that dose adjustment has been necessary.

- Clozapine levels typically change both over time and day to day, depending on many clinical factors. For example, changes in smoking and eating patterns can influence levels much more than a change that might result from switching from brand to generic.

- It is possible that some patients may be very sensitive to small changes in serum levels. Some dose adjustment may be necessary after the switch from brand to generic medication. These patients are sensitive to minor changes in medication use and other variables and have historically required closer monitoring and more frequent medication adjustments.

- Some physicians prefer to take pre-and post-switch clozapine levels. Although this is unnecessary for most patients, Medicaid will pay for these serum levels, if you believe they are clinically appropriate.

What criteria will be used to determine who can stay on brand name Clozaril®?

PA will be approved to continue on brand name Clozaril® only when the patient has:

- An adverse reaction to the generic drug(s).
- An allergic reaction to the generic drug(s).
- An actual or anticipated therapeutic failure of the generic drug(s).

Procedure for approval of brand name Clozaril®

1. If the patient actually experiences an adverse reaction, allergic reaction or therapeutic failure, document these facts in the patient's chart, complete the Food and Drug Administration (FDA)-approved MedWatch form and write a new prescription for use at the patient's pharmacy. The MedWatch form and prescription must be sent to the pharmacy or given to the recipient to take to the pharmacy. The pharmacy will process the PA request and contact you if additional information is necessary.

2. If you believe, based on the criteria listed above, that a patient should not be switched, contact the pharmacy before September 1, 2004.

3. You then have <u>two weeks</u> to complete the FDA MedWatch form (copy attached), documenting the justification for remaining on brand name Clozaril®. This form can also be obtained from the FDA website: <u>www.fda.gov/medwatch</u> or at the Prior Authorization Committee website: <u>http://www.pac.wisconsin.gov/</u>.

4. <u>After October 1, 2004</u> brand name Clozaril® will not be dispensed unless a MedWatch form has been completed and sent or faxed to the pharmacy.

5. Upon receipt of the MedWatch form, brand name Clozaril® may be dispensed for a two-week period pending a clinical review by nurses and psychiatrists working with the

Wisconsin Bureau of Mental Health and Substance Abuse Services and the Division of Health Care Financing. During this initial transition period, if the review takes more than two weeks, the Pharmacy will allow the patient a second refill of the brand name Clozaril®. Typically, this review will take less than 30 days.

6. A MedWatch form with no justification or explanation that applies to this specific patient will be rejected.

7. We anticipate that there will be only a few patients, based on past history, for whom switching to generic clozapine will entail significant risk. We anticipate authorizing continued use of brand medication in these circumstances.

If you have questions regarding the clinical criteria for approval of brand name Clozaril®, please contact one of the DHFS consultants at the information listed below. The Department of Health and Family Services has also designated two registered nurses with clinical experience in psychiatric services to support the implementation of this policy. You or your patients may also contact the DHFS nurses listed below with questions regarding this policy.

Questions regarding Medicaid administrative policies may be directed to Mark Moody, Administrator/Medicaid Director, at (608) 266-8922 or James Vavra, Budget and Policy Director, at (608) 261-7838.

Sincerely,

Ronald J. Diamond, M.D.
Consultant, DHFS, Bureau of Mental Health and Substance Abuse Services
Professor, Department of Psychiatry
University of Wisconsin
Medical Director, Mental Health Center of Dane County

Richard Carr, M.D.
Chief Medical Officer
Division of Health Care Financing

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Attachments